Rev 1: September 2018

FSN Ref: PERASAFE-IFU-FSN-012020 FSCA Ref: PERASAFE-IFU-FSCA-012020

Date: 18 MAR 2020

Urgent Field Safety Notice
Rely+On™ Perasafe™

For Attention of*:- Users of the device – Healthcare Professionals responsible for infection control measures involving the device – Distributors and Resellers of the Device – Individuals involved in purchasing the device.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Antec International Limited - relyondisinfection@lanxess.com - +44 (0) 1787 377 305 – Windham Road, Chilton Industrial Estate, Sudbury, Suffolk, CO10 5BX, United Kingdom

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Urgent Field Safety Notice (FSN)

Rely+On™ Perasafe™

Restriction on the maximum number of uses

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	High Level Disinfectant for use on invasive and non-invasive medical devices. 
1.	2. Commercial name(s)
	Rely+On™ Perasafe™
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not available
1.	4. Primary clinical purpose of device(s)*
	For disinfection of heat-labile medical device equipment, such as flexible endoscopes
1.	5. Device Model/Catalogue/part number(s)*
	All pack sizes: 16.2g sachets; 81g, 162 and 810g pots (see above picture)
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	All product that has not exceed the expiry date
1.	8. Associated devices
	Not applicable.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Instruction for Use leaflet (IFU) missing: 1). indication for maximum numbers of uses (20 immersions) and 2). indication to ensure thorough rinsing after pre-cleaning to remove any residual detergent
2.	2. Hazard giving rise to the FSCA*
	Increased risk of patient-to-patient transmission of pathogens resulting from reuse of treated medical devices due to detrimental effects on activity if: 1) used beyond 20 immersions, and 2). in contact with excessive amounts of detergent.
2.	3. Probability of problem arising
	No incidents have been reported but a residual risk cannot be eliminated, where an activated solution of Rely+On™ Perasafe™ is used beyond 20 immersion and where there is excessive organic challenge (e.g. instruments that have not been pre-cleaned) and/or detergent present.
2.	4. Predicted risk to patient/users
	Very low – internal screening has shown that solutions of Rely+On™ Perasafe™ remain effective past 20 immersions, but this data is not “state of the art” and cannot be used to demonstrate compliance with the essential requirements.
2.	5. Further information to help characterise the problem
	No issue is reported with product quality and Rely+On™ Perasafe™ will perform as expected. Product recall is not necessary.
2.	6. Background on Issue
	Manufacturer has been made aware of this risk and deficiency of the IFU during a routine audit by the Notified Body.
2.	7. Other information relevant to FSCA
	None

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Ensure that any associated protocols or operating procedures are updated according to account for the limitation on the maximum of 20 immersions	
3.	2. By when should the action be completed?	Without undue delay following receipt of this Field Safety Notice
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients’ previous results recommended? No *Not applicable*	

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	All subsequent manufacture of the device will include the updated IFU.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	*Not applicable*
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	*Not applicable*
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Antec International Limited**
	b. Address	**Windham Road, Chilton Industrial Estate, Sudbury, Suffolk, CO10 5BX, United Kingdom. Tel: +44(0) 1787 377 305**
	c. Website address	**relyondisinfection@lanxess.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.